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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,992	03/06/2002	Junzo Sunamoto	Yanagihara C-49A	8077

7590 02/23/2004

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EXAMINER

LEWIS, PATRICK T

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,992

Applicant(s)

SUNAMOTO ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/530,347.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Response dated November 26, 2003

1. In the Response filed November 26, 2003, claims 19-22 and 24-25 have been amended; claims 1-18 and 23 have been canceled. Applicant presented arguments directed to the rejection of claims 19-21 under 35 U.S.C. 102(b). Claims 19-22 and 24-25 are pending. An action on the merits of claims 19-22 and 24-25 is contained herein below.
2. The objection of claims 22-25 as being improper form has been rendered moot in view of applicant's amendments filed November 26, 2003.
3. The rejection of claims 19-21 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendments filed November 26, 2003.
4. The rejection of claims 19-21 under 35 U.S.C. 102(b) has been rendered moot in view of applicant's amendments filed November 26, 2003. Applicant's arguments with respect to claims 19-21 under 35 U.S.C. 102(b) have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 19-22 and 24-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyoshi et al. *Chemistry Letters* (1991), 7, 1263-1266 (Akiyoshi).

Claims 19-22 and 24-25 are drawn to a purified product of a polysaccharide containing a hydrophobic group having a content of at least 80% by weight of the polysaccharide containing the hydrophobic group, wherein the

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hydrophobic group is represented by formula (1), and wherein the content of an impurity product, in which both of the NCO groups in the diisocyanate are reacted with the hydroxyl group-containing hydrocarbon having 12-50 carbon atoms or with sterol, being no greater than 0.05% by weight.

Akiyoshi teaches a cholesterol-substituted polysaccharide derivative wherein pullulan is the polysaccharide which renders obvious the instantly claimed product (page 1263, last paragraph). The degree of substitution is 5.5 cholesterol groups per 100 glucose units (page 1264, first paragraph). The compounds are purified by dialysis using Seamless Cellulose Tube (page 1263, last paragraph). The compounds, which are seen to render obvious the instantly claimed compounds are those pullulan derivatives set forth in Fig. 1 wherein R = CHP. The polysaccharide derivative aggregates are employed as a carrier for various lipophilic drugs, proteins, nucleic acids, and so on (page 1266, last paragraph).

Aiyoshi differs from the instantly claimed invention in that Aiyoshi does not explicitly teach content of an impurity product in which both of the NCO groups in the diisocyanate are reacted with the hydroxyl group-containing hydrocarbon having 12-50 carbon atoms or with sterol being no greater than 0.05% by weight.

Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art

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suggest the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. Regarding the similar utility factor, both products are employed in encapsulating therapeutically active agents. Regarding the second factor, the two products do not differ in structure and Aiyoshi does indeed set forth a method for purifying the polysaccharide derivative. Since the Office does not have the facilities for preparing the claimed materials and comparing with prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. In the absence of some proof of a secondary nature to obviate the rejection as set forth supra, or of some specific limitations which would tip the scale of patentability in the favor of the instantly claimed invention, the instantly claimed product of a polysaccharide is indeed *prima facie* obvious.

Conclusion

9. Claims 19-22 and 24-25 are pending. Claims 19-22 and 24-25 are rejected. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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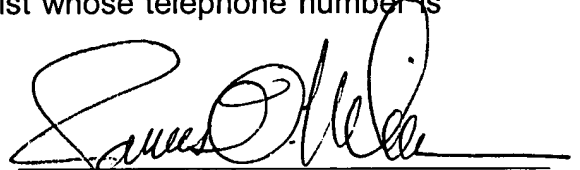
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
February 17, 2004